AUG 9 - 2005

510(k) Summary of Safety and Effectiveness
PhotoMedex Inc., VTRAC Excimer Lamp System K051428

1. GENERAL

- *Submitter (Applicant):* PhotoMedex, Inc.
  147 Keystone Drive
  Montgomeryville, PA, 18936
- *Contact Person:* Bob Rose (760) 602-3300
- *Date Prepared:* July 7, 2005

2. DEVICE NAME

- *Classification name:* **Ultraviolet lamp for dermatologic disorders; 21 CFR §878.4630 – Class II**
- *Common or usual name:* **Targeted (localized) UVB Excimer Lamp Phototherapy System**
- *Trade or proprietary name:* **VTRAC Excimer Lamp System**

3. LEGALLY MARKETED PREDICATE DEVICES

TheraLight UV120-2 UVA / UVB Phototherapy System
Cleared via K024020 and K022165

Lumenis BClear™
Cleared via K020591 and K021762

Levia Phototherapy System
Cleared via K040062

4. DEVICE DESCRIPTION

The VTRAC Excimer Lamp System is a self-contained non-invasive (non-ablating) dermatological phototherapy instrument that emits targeted (ultra-narrow) ultraviolet wavelength that is included in the UV-B region of the electromagnetic spectrum centered at 308 nm, which has been determined to effective for the treatment of skin conditions that respond favorably to UV-B, narrow band UV-B, and monochromatic UV-B phototherapy. UNB-UVB is emitted from a XeCl excimer lamp inside a handpiece used to apply targeted UVB energy to only areas that require treatment, thus allowing non-involved areas (healthy) of the skin to be spared from exposure.

5. INDICATIONS FOR USE

UVB phototherapy for skin conditions which include psoriasis, vitiligo, atopic dermatitis, and leukoderma.

6. SUBSTANTIAL EQUIVALENCE

The intended use for the VTRAC Excimer Lamp System is similar to the predicate devices identified in that the wavelength, energy, indicated used and safety considerations are within the current applications of UV-B phototherapy, or supported by published clinical data included in this application.

PhotoMedex believes the introduction of the VTRAC Excimer Lamp System poses no new issues of safety and is similar in intended use as compared to the predicates identified within this application.

7. SAFETY AND EFECTIVENESS; PRODUCT PERFORMANCE

The VTRAC Excimer Lamp System is designed, tested and are to be manufactured in accordance with both mandatory and voluntary standards, including 21 CFR PART 820 – the Quality System Regulation, EN60601-1, EN60601-1-2, EN 60601-1-4, EN ISO 14971, and UL2601-1 / UL60601-1. The inclusion of these standards will further ensure when the VTRAC Excimer Lamp System is used according to the instructions for use, that it is both safe and effective for the applications indicated.

8. CONCLUSIONS

Based on the information reviewed and provided within this application, PhotoMedex believes that the VTRAC Excimer Lamp System is substantially equivalent to the TheraLight UV120-2 UVA / UVB Phototherapy System, the Lumenis BClear™, and the Levia Phototherapy System, in that it is safe and effective as the legally marketed predicate devices, and that they share similar mechanisms for laser energy delivery and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 9 - 2005

Mr. Bob Rose
Director of Regulatory Affairs
and Quality Assurance
PhotoMedex, Inc.
147 Keystone Drive
Montgomeryville, Pennsylvania 18936

Re: K051428
Trade/Device Name: VTRAC Excimer Lamp System
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: II
Product Code: GEX
Dated: May 27, 2005
Received: June 1, 2005

Dear Mr. Rose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Buchwald
for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K051428**

Device Name:

VTRAC Excimer Lamp System

Indications For Use:

UVB phototherapy for skin conditions which include psoriasis, vitiligo, atopic dermatitis and leukoderma.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number 5051428